## REMARKS

Claims 17-33 are currently pending, with claim 17 being the only independent claim. Claim 17 has been amended. Support for the amendment to independent claim 17 may be found, for example, at pg. 2, lines 4-6 and at pg. 6, line 33 to pg. 7, line 2 of the specification as originally filed. No new matter has been added.

Claims 17-33 stand rejected under 35 U.S.C. §101 as directed to non-statutory subject matter. For the following reason, reconsideration and withdrawal of the rejection is respectfully requested.

The Examiner (pg. 5 of the Office Action) states that:

> Based on Supreme Court precedent and recent Federal Circuit Decisions, a §101 process must be tied to another statutory class (such as an apparatus) and must positively recite the subject matter being transformed by identifying the material that is being changed to a different state. Therefore, the method claims must positively recite the tied apparatus and must also recite the end result or physical transformation.

As discussed in more detail below, independent claim 17 positively recites an apparatus and an end result or physical transformation. Amended independent claim 17 recites, *inter alia*, a "non-invasive method for producing a local temperature increase within a body of material using focused sound signals in a target region ... said method comprising ... adapting the pressure-time signal such that the pressure-time course of the sound signals in the target region is adapted to a specific utilization of the non-linear propagation and attenuation properties of the material in the target region such that the non-invasively produced local temperature increase in the target region of the body of material produced by the adapted pressure-time signal is greater than a temperature increase produced by a sinusoidal pressure-time signal having the same power.

In addition, independent claim 17 recites "generating a sound signal in the target region non-invasively by radiating the sound signal from a sound emitter in response to a pressure-time signal". Therefore, independent claim 17 is tied to a specific apparatus, i.e., the sound emitter.

Independent claim 17 has been therefore amended such that it is tied to an apparatus, i.e., the sound emitter, and is limited to a practical application that produces a useful, tangible and concrete result, i.e., an increased temperature in the target region. In view of the foregoing, independent claim 17 recites statutory subject matter. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §101 are in order, and a notice to that effect is requested.

Claims 17-33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0077627 ("*Johnson*"). For the following reason, reconsideration and withdrawal of the rejection is respectfully requested.

Before discussing the cited prior art and the Examiner's rejections of the claims in view of that art, a brief description of the subject matter described in the present application is deemed appropriate to facilitate understanding of the arguments for patentability. The description is not meant to argue unclaimed subject matter.

The claimed invention is non-invasive method for directly improving the localization of heating that is provided to treat internal tumors with the targeted use of non-linear ultrasonic propagation effects generated by a sound transmitter that is external to the body in which the target region resides. The method permits a drastic reduction of the balancing associated with metering (i.e., dosing), even with deeply lying tumors. Consequently, a practical way to treat tumors located deep within a patient is achieved without expensive on-line monitoring. The method also permits an improved localization of the dosage such that a significantly lower

thermal loading of the tissue located in front of the tumor is achieved, along with the simultaneous necrotization of the tumor. Consequently, the delay between the time that individual necrosis spots are treated with the dosage may be significantly reduced, which leads to a noticeable optimization of the ultrasonic thermotherapy that is rendered, the practical handling of the therapy, as well as contributing to the further care of the patient by alleviating the recovery associated with invasive conventional surgical methods (see pg. 5, 26-35 of the specification as originally filed).

Independent claim 17 has been amended to recite, *inter alia*, the steps of "generating a sound signal in the target region non-invasively by radiating the sound signal from a sound emitter in response to a pressure-time signal" and "adapting the pressure-time signal such that the pressure-time course of the sound signals in the target region is adapted to a specific utilization of the non-linear propagation and attenuation properties of the material in the target region such that the non-invasively produced local temperature increase in the target region of the body of material produced by the adapted pressure-time signal is greater than a temperature increase produced by a sinusoidal pressure-time signal having the same power".

*Johnson* discloses a method and an apparatus for minimally invasive surgery. Figure 1 of Johnson clearly shows that the elongated member 12 of the probe 10 is inserted into a patient to treat a tumor in an invasive manner, even though *Johnson* asserts that the disclosed treatment is minimally invasive. The Examiner-cited sections of *Johnson* describe treatment treatment signals that are sent through the probe 12 which is inserted in the body to the target region.

In contrast, the claimed invention is directed to provide non-invasive treatment of a patient. That is, the adapting step of now-amended independent claim 17 recites that "the non-invasively produced local temperature increase in the target region of the body of material produced by the

adapted pressure-time signal is greater than a temperature increase produced by a sinusoidal pressure-time signal having the same power". *Johnson* fails to teach or suggest this limitation.

Moreover, the method of independent claim 17 eliminates the requirement to perform any measurements in the target region. Consequently, unlike the method of *Johnson* that requires, *corporal* invasive procedures, the method of the independent claim 17 is completely extra-corporal and non-invasive.

In view of the foregoing, amended independent claim 17 is patentable over *Johnson*. Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are therefore in order, and a notice to that effect is respectfully requested.

In view of the patentability of independent claim 17, dependent claims 18-33 are also patentable over the prior art for the reasons set forth above, as well as for the additional recitations contained therein.

Dependent claim 33 specifically recites "wherein the sound emitter is entirely outside the body of material during the step of generating and adapting". Since the probe of *Johnson* is inserted into the body to generate the treatment signal at the target region, *Johnson* fails to disclose this limitation.

Based on the foregoing remarks, this application is in condition for allowance. Early passage of this case to issue is respectfully requested.

Should the Examiner have any comments, questions, suggestions, or objections, the Examiner is respectfully requested to telephone the undersigned in order to facilitate reaching a resolution of any outstanding issues.

It is believed that no fees or charges are required at this time in connection with the present application. However, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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Dated: November 6, 2008